



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: CEFALI, EUGENIO  
Serial No.: 08/960,557  
Filing Date: 31 October 1997  
Docket Number: 50454-56103USCIP  
Title: METHODS FOR TREATING HYPERLIPIDEMIA WITH  
INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS  
HAVING UNIQUE BIOPHARMACEUTICAL CHARACTERISTICS

**COMMISSIONER FOR PATENTS**

P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

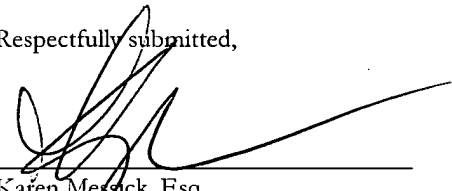
Applicants and their attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97(c) hereby submit these publications for the Examiner's consideration. This Statement is being filed after the first Official Action under 37 CFR §1.97(c)(2). Please charge our deposit account number 50-2543 the amount of \$180.00 as specified in 37 CFR § 1.17(p). A full copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicant understands the Examiner will make an independent evaluation of the cited publications. No additional costs are believed to be due in connection with the filing of this disclosure. However, please charge any necessary fees to our Deposit Account No. 12-0448. For this purpose we enclose a duplicate copy of this document.

10/23/2003 EFLORES 00000127 502543 08960557

01 FC:1806 180.00 DA

Respectfully submitted,

  
Karen Messick, Esq.  
Registration Number 46,256  
Attorney for Applicants

Kos Pharmaceuticals, Inc.  
1001 Brickell Bay Drive  
25<sup>th</sup> Floor  
Miami, FL 33131  
Tel.: 305.523.3663  
Fax: 305.377.4076

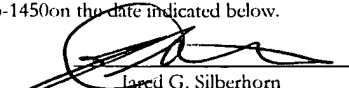
Date: 10/17/03

**CERTIFICATION UNDER 37 C.F.R., §1.8**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

10/17/03

Date

  
Jared G. Silberhorn



Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>Substitute for form 1449B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			<b>Application Number</b>	08/960557	
			<b>Filing Date</b>	10/31/1997	
			<b>First Named Inventor</b>	Cefali	
			<b>Group Art Unit</b>		
			<b>Examiner Name</b>		
<b>Sheet</b>	1	<b>of</b>	1	<b>Attorney Docket Number</b>	50454-56103USCIP

<b>OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS</b>			
<b>Examiner Initials*</b>	<b>Cite No.<sup>1</sup></b>	<b>Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.</b>	<b>T<sup>2</sup></b>
	1	Dialog File 226: Trademarkscan(r)-US FED: Accession number 73/838497	
	2	McCarthy on Patents, Sec. 19.110	
	3	199 U.S.P.Q. 824 (Endo Laboratories, Inc. v. Fredericks, 08/18/1978)	
	4	KEENAN, et al., "A Clinical Trial of Oat Bran and Niacin in the Treatment of Hyperlipidemia", Jour. Fam. Prac., 34:3, 313-317 (1992)	
	5	KNOPP, et al., "Contrasting Effects of Unmodified and Time-Release forms of Niacin on Lipoproteins in Hyperlipidemic Subjects: Clues to Mechanism of Action of Niacin", Metabolism, 34:7, 642-650 (1985)	
	6	Letter to Applicant from U.S. Department of Health and Human Services dated 07/28/1997	

RECEIVED  
OCT 24 2003  
TECH CENTER 1600/2500

<b>Examiner Signature</b>		<b>Date Considered</b>	
-------------------------------	--	----------------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.